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DEC 11 2002

510(k) Summary K023597

Intended Use

The Access® OV Monitor assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CA 125 antigen levels in human serum and plasma, using the Access® Immunoassay Systems. This device is indicated for use in the measurement of CA 125 antigen to aid in the management of ovarian cancer patients. Serial testing for patient CA 125 antigen concentrations should be used in conjunction with other clinical methods used for monitoring ovarian cancer.

Summary of Studies

Specificity: There was no significant interference from therapeutic drugs or similar compounds using the Access OV Monitor. The following compounds were tested: doxorubicin at 100 µg/mL, amthopterin at 500 µg/mL, carboplatin at 1000 µg/mL, cyclophosphamide at 1000 µg/mL, 5-fluorouracil at 1000 µg/mL, cisplatin at 2000 µg/mL, melphalan at 100 µg/mL, acetominopehn at 200 µg/mL, aspirin at 500 µg/mL, paclitaxel at 10 ng/mL, biotin at 50 ng/mL and vitamin D2 at 1 U/mL.

In addition, there was no significant interference (<10% change) from potential sample contaminants (total protein at 9%, bilirubin at 20 mg/dL, hemoglobin at 1000 mg/dL, and triglycerides at 1800 mg/dL).

Analytical Sensitivity: The lowest detectable level of CA 125 antigen distinguishable from zero (Access® OV Monitor Calibrator S0) is 0.2 U/mL. An analytical sensitivity of 0.5 U/mL will be claimed in the labeling. Samples can be accurately measured between the lower limit of detection and the highest calibrator value (approximately 0.5 U/mL and 5,000 U/mL).

Recovery: Linearity studies performed by diluting 6 human serum samples at various levels with Access® OV Monitor Zero Calibrator provided an average recovery of 107%, with individual recoveries ranging from 100% to 118%.

Precision: Within-run assay imprecision was tested for concentrations from approximately 24 to 2962 U/mL. The within run imprecision ranged from 1.3% CV to 2.4% CV. Between-run assay imprecision ranged from 3.3% CV to 6.0% CV. Total imprecision ranged from 3.9% CV to 6.0% CV.

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Correlation: A comparison of OV Monitor values from 290 samples, ranging from approximately 0 to 600 U/mL, run with both the Access® OV Monitor immunoassay and the Abbott Axsym CA 125 assay demonstrated an acceptable correlation coefficient of: r = 0.9871; and a bias with a slope of y = 1.197 + (-0.985) across the range of the Axsym assay (approximately 0 – 600 U/mL).

Clinical Data: The data generated demonstrates comparable clinical sensitivity and clinical specificity for the Access OV Monitor and the Abbott Axsym CA 125 assays. The clinical sensitivity and specificity were calculated at: Sensitivity = 84.4% (95% confidence interval = 71.2% - 92.3%); Specificity = 82.5% (95% confidence interval = 82.5% - 90.0%).

Results from 20 female subjects who where diagnosed with ovarian cancer (stages I to IV) and who were monitored (7 months to 53 months) over the course of disease demonstrate that CA 125 concentration obtained with the Access OV Monitor assay were comparable and paralleled those results obtained with the FDA cleared predicate device.

Conclusion

The data generated demonstrates acceptable non-clinical (laboratory) performance, and good correlation between the Access OV Monitor assay and the Abbott Axsym CA 125 assay. Clinical sensitivity and clinical specificity for the Access OV Monitor and the Abbott Axsym CA 125 assays were found to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 11 2002

Ms. Mara Caler
Regulatory Affairs
Beckman Coulter, Inc.
4300 N. Harbor Blvd
Fullerton, CA 92835

Re: k023597
Trade/Device Name: Access® OV Monitor
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-Associated Antigen Immunological Test System
Regulatory Class: Class II
Product Code: LTK
Dated: November 25, 2002
Received: November 27, 2002

Dear Ms. Caler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (K023597):

Device Name: Access® OV Monitor

Indications For Use:

The Access® OV Monitor assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CA 125 antigen levels in human serum and plasma, using the Access® Immunoassay Systems. This device is indicated for use in the measurement of CA 125 antigen to aid in the management of ovarian cancer patients. Serial testing for patient CA 125 antigen concentrations should be used in conjunction with other clinical methods used for monitoring ovarian cancer.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

J P Reeves for J. Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number

Prescription Use ✓ OR Over-The Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)